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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/641,149	08/15/2003	Allan J. Tobin	704611-3001	9827
7590 10/23/2006				
BINGHAM McCUTCHEN, LLP				
Three Embarcadero Center				
San Francisco, CA 94111-4067				
		EXAMINER		
		ROBINSON, HOPE A		
		ART UNIT		PAPER NUMBER
		1652		

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/641,149

Applicant(s)

TOBIN ET AL.

Examiner

Hope A. Robinson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/9/06.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>9/6/06</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/24/06</u> . | 6) <input type="checkbox"/> Other: _____   |

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## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.
2. Applicant's response to the Office Action mailed March 22, 2006 on August 9, 2006, is acknowledged. The Terminal Disclaimer filed on August 9, 2006 have been received and entered.

### ***Claim Disposition***

3. Claim 39-42 are pending and are under examination.

### ***Information Disclosure Statement***

4. The Information Discloser Statement remains objected to because references filed in the parent application remain unable. As previously stated only the references, which appeared on the face of the issued patent have been considered at this point. Please note that the citations for references 4-5 of sheet 2 are incomplete and only give a title and section information. Applicant is urged to resubmit the references for consideration.

In addition, the Information Disclosure Statement filed on July 24, 2006 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action. Note however, that references AV,

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AW and AX have been lined through because these references are improper citations, no date or author is cited. Applicant is urged to resubmit these for consideration.

***Withdrawn-Specification Objections***

5. Previous objection to the specification are withdrawn by virtue of submission of an amendment.

***Maintained and Amended-Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 39-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NOS: 5 and 8, does not reasonably provide enablement for any fragments thereof or an unlimited amount of epitope recognized by autoantibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining

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whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)).

The factors most relevant to the instant invention are discussed below.

The claims are directed to an isolated nucleic acid sequence encoding a polypeptide having an amino acid sequence consisting of a sequence present in the glutamic acid decarboxylase 65 of SEQ ID NO:5 or SEQ ID NO:8 and possessing at least one epitope for an autoantibody to GAD65 (see claim 39 for example). Claim 39 recites the open language "having" and is directed to a polypeptide contained in SEQ ID NO:5 or 8 and there is no indication of what said polypeptide looks like structurally. No correlation is made between structure and function, although the claim recites "that said polypeptide possesses at least one epitope to an autoantibody of GAD65. Note that there is no limit on the number of epitopes or a demonstration of all the fragments encompassed in claim 39 possessing said properties. The disclosure reveals that autoantibodies from individual patients detect the GAD<sub>65</sub> protein encoded by the entire cDNA sequence of the instant invention, and that the greatest differences between GAD<sub>65</sub> and GAD<sub>67</sub> are in the 100 amino terminal amino acids. The disclosure does not reveal which specific portions of GAD<sub>65</sub> constitute epitopes that are recognized by autoantibodies, i.e., what features define a single epitope. An additional problem is that one does not *a priori* know that all sera with GAD<sub>65</sub> autoantibodies will recognize the identical epitopes on the protein.

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Thus, different batches of antisera could fail to detect an epitope recognized by a different batch of autoantibodies. Thus the instant specification is not commensurate in scope with the claims and a skilled artisan would have to engage in undue experimentation to practice the claimed. Further, the art is highly unpredictable. It is not clear that any random set of autoantisera will detect the same epitopes as other autoantisera. Applicants have revealed that autoantibodies from individual patients detect the GAD<sub>65</sub> protein encoded by the entire cDNA sequence of the instant invention, and that the greatest differences between GAD<sub>65</sub> and GAD<sub>67</sub> are in the 100 amino terminal amino acids. The disclosure does not reveal which specific portions of GAD<sub>65</sub> constitute epitopes that are recognized by autoantibodies, i.e., what features define a single epitope. An additional problem is that one does not *a priori* know that all sera with GAD<sub>65</sub> autoantibodies will recognize the identical epitopes on the protein. Thus, different batches of antisera could fail to detect an epitope recognized by a different batch of autoantibodies.

There is but a single working example, a full-length cDNA and the assertion that the greatest differences between GAD<sub>65</sub> and GAD<sub>67</sub> are in the 100 amino terminal amino acids. A great deal of experimentation would appear to be necessary to determine which subsequences encoding SEQ ID NOS: 2 or 3 would produce peptides that possess epitopes that react with autoantibodies. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, practicing the claimed invention would constitute undue experimentation.

***Withdrawn-Claim Rejections***

7. Previous rejection to claims for Obvious-type Double Patenting is withdrawn by virtue of submission of a Terminal Disclaimer.

***Response to Arguments***

8. The response filed on August 9, 2006 has been considered, however, is not fully persuasive. The rejection under 35 U.S.C. 112, first paragraph remains and has been amended to address issue not previously raised. The response on page 5 states that enablement is not precluded by the necessity of some experimentation, the only requirement is that such experimentation must not be undue. Applicant points to a number of references cited on the IDS (see pages 5-8), for example the Patel reference stating that 10 immunogenic regions of GAD65 have been identified. The references cited have been considered, however, are not persuasive as the claimed invention is not limited to the disclosure in the art. The claims broadly read on an unlimited amount of epitopes and a protein fragment contained in the GAD65 structure and no guidance is provided nor a direct correlation between structure and function made.

***Conclusion***


9. No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope A. Robinson   
Primary Patent Examiner  
AU 1652

**HOPE ROBINSON**  
**PATENT EXAMINER**